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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,958	09/18/2000	Iya Trakht	60240/JPW/SHS	4881

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/30/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,958

Applicant(s)

TRAKHT ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 17 is/are allowed.
- 6) ☐ Claim(s) 1-6, 8 and 10-16 is/are rejected.
- 7) ☒ Claim(s) 9 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 13
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: OFFICE ACTION

DETAILED ACTION

1. Claims 1-18 are pending and under examination.
Claims 6 and 16 have been amended.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains some NEW GROUNDS of rejection.

Specification

4. The disclosure is objected to because of the following informalities:
 - a. The specification should add the corresponding SEQ ID Nos: to the sequences in the specification, for example page 20, lines 27 and 31, page 26, page 81, page 94, page 95 and in the Brief description of the Drawings and in the abstract. Applicant is requested to review all pages of the specification for the listed objection as they appear to be numerous.
 - b. The specification is objected to because on page 95, line 22-23 the specification states "As used herein, "whole TIP-2 antigen protein" comprises the amino acid sequence shown in Figure 23", however, Figure 23 does not show any amino acid sequence.
 - c. Applicant is reminded of the proper language and format for an abstract of the disclosure.

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The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

Appropriate correction is required.

Rejections Withdrawn

5. The rejection of claims 1-18 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the deposit of 27.B1 and 27.F7 and that all assurances have been met.

6. The rejection claims 6 and 16 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the amendments to the claims and the amended term "domain" is being interpreted to mean any part of the TIP-2 protein.

Response to Arguments/NEW GROUNDS of Rejection

7. The rejection of claims 1, 2, 6, 8, 10-16 under 35 U.S.C. 103(a) as being unpatentable over De Vries et al (PNAS 95:12340-12345, 1998) and Rousset et al (Oncogene 16:643-654, 1998) and as evidenced by the specification, and further in view of Campbell (Monoclonal antibody technology, Elsevier Science Publishers, pages 1-32, 1986) and Harlow et al (antibodies, A laboratory manual, Cold Spring Harbor Laboratory, page 322, 1988) is maintained and made again. Claims 6 and 16 are being added to this rejection because of the amendment to the claims reciting "domain" and because of the indefinite nature of this term (see 112 second below) the term is being interpreted as being any part of the protein to which the antibodies 27.B1 and 27.F7 bind which includes cross reactivity.

The response filed 12/26/02 has been carefully considered but is deemed not to be persuasive. The response states that the claims are not merely to an antibody that binds to TIP-2 antigen, but rather to one that binds to TIP-2 antigen specifically associated with the surface of tumor cells and this element is not taught in any of the cited references (see page 38-39 of response) and there is no motivation to combine the teachings and that although TIP-2 had been previously described, the examiner has not pointed to any examples of monoclonal antibodies to this protein having been made prior to the instant invention (see pages 39-40 of response) and the tumor specificity of TIP-2 was clearly an unexpected and surprising result and therefore could not have been a reasonable expectation of success (see page 40 of response). In response to these arguments, there is clear motivation to combine the references as stated in the

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Office Action because Campbell et al teach "It is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (see page 29). Thus it would have been obvious to produce monoclonal antibodies for the reason given by Campbell. Applicants are reminded that this is a 103 rejection and as such it is the combination of references that render the invention obvious. Thus the combination of references produce the monoclonal antibodies to TIP-2. Although the claims require the TIP-2 to be on the surface of a tumor cell, it is obvious that the antibodies produced by the combination of references would bind to TIP-2 and since TIP-2 is on the surface of the tumor the antibodies would obviously bind and one would have a reasonable expectation of success that the antibodies bind to TIP-2 since that was the antigen that the antibodies were made against. In addition, it would have been obvious that in making the monoclonal antibodies against the entire protein of TIP-2 this would result in antibodies binding to all regions of the protein and as such antibodies to all the "domain" of TIP-2.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

8. The rejection of claims 1-6, 8, 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Vries et al (PNAS 95:12340-12345, 1998) and Rousset et al (Oncogene 16:643-654, 1998) and as evidenced by the specification, and further in view of Campbell (Monoclonal antibody technology, Elsevier Science Publishers, pages

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1-32, 1986) and Harlow et al (antibodies, A laboratory manual, Cold Spring Harbor Laboratory, page 322, 1988) as applied to claims 1, 2, 8, 10-15 above, and further in view of Adair et al (WO 91/09967, published 7/11/91) and Green et al (Nature genetics 7:13-21, 1994) is maintained and made again. Claims 6 and 16 are being added to this rejection because of the amendment to the claims reciting "domain" and because of the indefinite nature of this term (see 112 second below) the term is being interpreted as being any part of the protein to which the antibodies 27.B1 and 27.F7 bind which includes cross reactivity.

The response filed 12/26/02 has been carefully considered but is deemed not to be persuasive. The response states the remarks are incorporated herein in connection with the non-obviousness set forth above and that there was no motivation to combine the references to produce a monoclonal antibody to tumor-specific TIP-2 nor would there be motivation to make chimeric, humanized or human variants (see page 41-42 of response). In response to these arguments, the arguments above are reiterated for this rejection. In addition, the motivation to combine the references to produce chimeric, human, and humanized antibodies is stated in the Office Action because Rousset et al teach the TIP-2 protein interacts with the HTLV-1 Tax oncoprotein and the oncoprotein has been established to be associated with induction of tumors in transgenic mice (see page 643) and TIP-2 is a human protein that interacts with HTLV-1. Thus, since the TIP-2 protein is associated with an oncoprotein it would be obvious to produce a human, humanized, or chimeric antibody to the protein.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

The following are some additional NEW GROUNDS of rejection

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 6 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 16 are indefinite for reciting “binds to the same domain of TIP-2” because the phrase is not clear. It is not clear what the term “domain” is referring to since the specification does not clearly define the term. Apparently the TIP-2 protein has not been described in the specification as having multiple domains such as would be the case for a protein with a cytoplasmic or membrane domain or multiple domain protein. It is unclear what domain the claims are being directed to. Is the “domain” the entire protein or some specific region of the protein?

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 6 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6 and 16 have been amended to recite "domain". The response filed 12/30/02 has been carefully considered but is deemed not to be persuasive because the response did not address where support for the term can be found in the specification as originally filed. The examiner does not apparently find support for the term in the specification. Applicants are required to provide specific support for the limitation or remove it from the claims.

Conclusion

13. Claims 7 and 17 are in condition for allowance. Claims 9 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

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Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', written in a cursive style.